REMARKS

I. Preliminary Remarks

In the Office Action, Claims 1-13 are pending and under examination. Claims 14-51 are withdrawn in response to a requirement for restriction, with traverse and without prejudice, in an effort to favorably advance prosecution of the present application. Applicants reserve the right to petition for rejoinder should the circumstances allow, or to pursue the subject matter of the withdrawn claims in divisional applications.

After entry of this paper, Claims 1, 3-4, and 11 are amended, and Claim 2 is canceled. Thus, Claims 1 and 3-13 are under consideration. Support for the amendments is found throughout the specification. The amendments do not include new matter. In this response, Applicants addresses each of the Examiner's rejections. Reconsideration and withdrawal of the rejections are solicited for the reasons set out below. Applicants therefore respectfully submit that the present application is in condition for allowance. Favorable consideration of all pending claims is respectfully requested.

This Response is timely filed. The USPTO is given authorization to charge Deposit Account No. 16-1445 for any fees necessary with the submission of this Response.

II. Patentability Arguments.

A. Sequence Compliance Rejection May be Properly Withdrawn.

The Examiner stated that the instant "application fails to comply with the requirements of 37 C.F.R. 1.821-25 for the reasons set forth on the ... Notice to Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures... 'CRF DOES NOT MATCH APPLICATION SPECIFICATION – APPLICANT MUST CORRECT'. Accordingly, Applicant must fix these compliance issues. A statement under 37 CFR 1,821(f) stating that the original CRF and sequence listing are the same must be provided."

Applicants thank Examiner for explaining in a phone message on February 28, 2007 the issues involved in this rejection. As instructed, included with this response is a new computer readable copy (CRF) containing the sequence listing as filed with the application and the required statement that the CRF and the paper copy of the sequence listing are identical. Also

included is a new paper copy of the sequence listing which was generated with Patent In using the sequences submitted in the application. No new matter is added with this submission.

B. The Anticipation Rejections under 35 U.S.C. §102(b) May Properly Be Withdrawn.

A patent is invalid for anticipation under 35 U.S.C. 102(b) if a single prior art reference identically discloses each and every limitation of the invention as set forth in the claims. (Lewmar Marine, Inc. v. Barient, Inc., 827 F.2d 744, 747 (Fed. Cir. 1987)). The prior publication must disclose in an enabling manner the invention that is in question. The exclusion of a claimed element, no matter how insubstantial or obvious, from a reference is enough to negate anticipation. (Connell v. Sears, Roebuck & Co., 220 U.S.P.Q. 193, 1098 (Fed. Cir. 1983)). Applicant respectfully submits that these criteria are not met in the Examiner's rejection. The claims, therefore, are not anticipated by the references.

1. The Anticipation Rejection of Claims 1-5, and 9 under 35 U.S.C. §102(b) May Properly Be Withdrawn.

Claims 1-5 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Charles, et al., (WO 92/17587). Applicants respectfully traverse this rejection.

Claim 1 is directed to a vaccine composition comprising a *Bordetella bronchiseptica* p68 antigen, wherein the antigen is produced recombinantly, and an adjuvant to protect dogs against *Bordetella bronchlseptica*. Charles, et al., disclose the sequence of the p68 antigen. However, the intent to vaccinate dogs represents a limiting feature of Claim 1 of the instant application because the intended use is expressed in the claim. Charles, et al., do not disclose a vaccine composition comprising recombinantly produced p68 antigen for dogs. Also, they do not teach or disclose that said p68 antigen sequence can be use for a vaccine composition effective to protect dogs against *Bordetella bronchiseptica*.

Applicant traverses the Examiner's suggestion that "the term 'vaccine effective to protect dogs against Bordetella bronchispetica' is an intended use only" and adds no element to the pending claims. A textbook definition of vaccine can be found in Veterinary Vaccinology, P.-P. Pastoret, J Blancou, P. Vannier & C. Vershueren, Editors, Elsevier Publications, copyright 1997, page 135. Vaccines are agents that are employed to induce a specific, systemic and/or local, humoral and cellular immune response, to initiate or enhance protection of the host against viral, bacterial or parasitic attack. They play a key role in the prevention of viral or bacterial diseases

and in limiting their consequences." A definition may even be found from the CAFC, "A vaccine 'must by definition trigger an immunoprotective response in the host vaccinated; mere antigenic response is not enough." *In re Wright,* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). A vaccine must impart some type of protection to the host. It is not a word that adds no element to the claims.

One should recognize that delivery to a host of live pathogenic bacteria would prove to be deleterious without the prior steps of inactivation or attenuation of the bacteria, or isolating a specific antigen from the bacteria. Thus, important modifications of live bacteria must be made in order to create a useful vaccine. A few well-known bacteria where vaccines have never been made in spite of strenuous efforts to do so include

- *Mycoplasma bovis* – respiratory and mammary pathogen of cattle - existing vaccines have poor/no efficacy. This is despite the fact that *Mycoplasma hyopneumoniae* in pigs has been used to make great vaccines.
- *Mannheimia haemolytica* – respiratory pathogen of cattle.
- *Mycobacteria tuberculosis* – causes human tuberculosis.
- *Streptococcus pyogenes* ("flesh-eating bacteria") – causes infection and death.
- *Treponema pallidum* – causes syphilis.
- *Neisseria gonorrhea* – causes Gonorrhea.

Success in producing a vaccine against an organism in one species does not assure such success in another species. Therefore, the vaccine of the present invention, comprising a recombinantly produced p68 antigen and an adjuvant effective to protect dogs against *Bordetella bronchiseptica*, is significantly distinguishable over the prior art.

The p68 amino acid sequence recited by Charles, et al., in claim 1 encodes for the mature polypeptide. However, they did not enable this sequence/polypeptide. What they actually cloned was the entire gene, including the 5' portion encoding the signal sequence (see Results and Fig. 1). They found that "A Western blot of an SDS-PAGE gel of *E. coli* TG1 harbouring pBD881 surprisingly did not produce a detectable 94 kDa higher molecular weight band, but instead produces a pair of stronger bands at around 69kDa and 68kDa." (emphasis added) In other words, they cloned the entire gene and clearly expected to express a 94 kDa polypeptide. The resulting expressed polypeptide, however, was the processed (mature) p68 protein. Slide

agglutination assays using monoclonal antibodies suggested that the heterologous protein (p68) was surface bound. See page 12, line 25 through page 13, line 3. The most plausible scientific explanation for this was that the *E. coli* host cells recognized the signal sequence, transported the precursor protein to the membrane where it became anchored, and subsequently cleaved the signal sequence. The end result was a membrane-anchored, surface-exposed p68 protein in *E. coli*. Those skilled in the art would recognize that membrane-anchored proteins are not useful subunit vaccine antigens, as they are insoluble and difficult to purify away from host cell and membrane contaminants. This unsolved problem has been overcome by the invention of the present application. The Applicants have enabled the cloning and expression of p68 lacking its signal sequence, which resulted in recombinant p68 without a signal sequence to be expressed inside the *E. coli* host cell. The recombinant protein was readily purified from the host cell, adjuvanted, and proven to be efficacious as a vaccine.

As stated above, a rejection of the claims for anticipation requires that the cited reference disclose each and every element of the claim in an enabling manner. There must be no difference between the subject matter of the claim and the disclosure of the reference. The exclusion of a claimed element, no matter how insubstantial or obvious, from a reference is enough to negate anticipation. Charles, et al., do not anticipate the claimed invention because they fail to disclose each and every element of the claim in an enabling manner.

Thus, because Charles, et al., do not enable a vaccine composition comprising p68 antigen for dogs against *Bordetella bronchiseptica*, wherein the antigen is produced recombinantly, they do not teach each and every limitation of Claim 1 of the instant application. Claims 3-5 and 9 either depend from Claim 1 or from a claim that depends from Claim 1. These claims further delineate the vaccine composition of Claim 1; they embody all the elements of Claim 1. Accordingly, the subject matter of Claims 1, 3-5 and 9 is not anticipated by Charles. Claim 2 is canceled rendering this rejection of this claim moot. Based on the remarks presented herein, the rejection of Claims 1-5 and 9 under 35 U.S.C. §102(b) is overcome. Withdrawal of the rejection is therefore respectfully requested.

2. The Anticipation Rejection of Claims 1-5 under 35 U.S.C. §102(b) May Properly Be Withdrawn.

Claims 1, 2, 3, 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Montaraz et al (Infection and Immunity, 1985, 47: 744-751). Applicants respectfully traverse this rejection.

Claim 1 is directed to a vaccine composition comprising a *Bordetella bronchiseptica* p68 antigen, wherein the antigen is produced recombinantly, and an adjuvant to protect dogs against *Bordetella bronchiseptica*. Montaraz, et al., merely identify and purify a 68 kD protective protein antigen from *Bordetella bronchiseptica*. (See, e.g., Abstract) In their studies, they used native p68 purified from *B. bronchiseptica* cells (see Materials and Methods section beginning on page 744); they did not use recombinantly produced p68 as is done in the instant application (see amended claim 1). The intent to vaccinate dogs represents a limiting feature of Claim 1 because the intended use is expressed in the claim. However, Montaraz, et al., do not disclose a vaccine composition comprising p68 antigen for dogs. Also, they do not teach or disclose that the p68 antigen sequence can be use for a vaccine composition effective to protect dogs against *Bordetella bronchiseptica*. The authors admit that even the possibility of using 68 kD protein as a vaccine for pigs still "requires extensive investigation." See page 750, right column, first paragraph.

As stated above, a rejection of the claims for anticipation requires that the cited reference disclose each and every element of the claim. There must be no difference between the subject matter of the claim and the disclosure of the reference. The exclusion of a claimed element, no matter how insubstantial or obvious, from a reference is enough to negate anticipation. Montaraz, et al., fail to disclose each and every element of the claim.

Thus, because Montaraz, et al., do not teach a vaccine composition comprising p68 antigen for dogs against *Bordetella bronchiseptica*, wherein the p68 antigen is produced recombinantly, they do not teach each and every limitation of Claim 1 of the instant application. Claims 3-5 either depend from Claim 1 or from a claim that depends from Claim 1. These claims further delineate the vaccine composition of Claim 1; they embody all the elements of Claim 1. Accordingly, the subject matter of Claims 1 and 3-5 is not anticipated by Montaraz. Claim 2 is canceled rendering this rejection of this claim moot. Based on the remarks presented herein, the rejection of Claims 1-5 under 35 U.S.C. §102(b) is overcome. Withdrawal of the rejection is therefore respectfully requested.

3. The Anticipation Rejection of Claims 1-5 under 35 U.S.C. §102(b) May Properly Be Withdrawn.

Claims 1, 2, 3, 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Novotny et al (Infection and Immunity, 1985, 47: 744-751). Applicants respectfully traverse this rejection.

Examiner recited "Infection and Immunity, 1985, 47: 744-751" for the Novotny article. However, the author of this reference was Montaraz. Based on the page numbers given in Examiner's comments in the Office Action, it appears that the reference should be "Infection and Immunity, 1985, 50: 190-198" for which the author is Novotny. Applicants' based their response on the latter citation.

Claim 1 is directed to a vaccine composition comprising a *Bordetella bronchiseptica* p68 antigen, wherein the antigen is produced recombinantly, and an adjuvant to protect dogs against *Bordetella bronchiseptica*. Novotny, et al., merely evaluate *Bordetella bronchieptica* vaccines for pigs and identify that a p68 antigen appears to be an important immunogen of *Bordetella bronchiseptica.* (See, e.g., Abstract and page 197, left column, paragraph 1) The vaccines used in this reference were whole cell preparations (see page 192, right column), not compositions comprising purified p68, wherein the p68 was produced recombinantly. Novotny only used the p68 in the ELISA assay. (see page 191, right column) In addition, the intent to vaccinate dogs represents a limiting feature of Claim 1 because the intended use is expressed in the claim. However, nowhere does Novotny disclose a vaccine composition comprising recombinantly produced p68 antigen to protect dogs against *Bordetella bronchiseptica,* as recited in Claim 1. In fact, Novotny expressly states that "vaccines from porcine strains performed poorly against challenge by canine strains and vice versa." See page 197, right column, lines, 9-11.

As stated above, a rejection of the claims for anticipation requires that the cited reference disclose each and every element of the claim. There must be no difference between the subject matter of the claim and the disclosure of the reference. The exclusion of a claimed element, no matter how insubstantial or obvious, from a reference is enough to negate anticipation. Novotny, et al., fail to disclose each and every element of the claim.

Thus, because Novotny, et al., do not teach a vaccine composition comprising p68 antigen for dogs against *Bordetella bronchiseptica*, wherein the p68 antigen is produced

recombinantly, they do not teach each and every limitation of Claim 1 of the instant application. Claims 3-5 either depend from Claim 1 or from a claim that depends from Claim 1. These claims further delineate the vaccine composition of Claim 1; they embody all the elements of Claim 1. Accordingly, the subject matter of Claims 1 and 3-5 is not anticipated by Novotny. Claim 2 is canceled rendering this rejection of this claim moot. Based on the remarks presented herein, the rejection of Claims 1-5 under 35 U.S.C. §102(b) is overcome. Withdrawal of the rejection is therefore respectfully requested.

C. The Obviousness Rejection of Claims 6-8 and 10-13 under 35 U.S.C. §103(a) May Be Properly Withdrawn.

As stated in the MPEP (§2141), to support an obviousness rejection, four basic criteria must be met. These are (A) The claimed invention must be considered as a whole; (B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination; (C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and (D) Reasonable expectation of success is the standard with which obviousness is determined. Clearly for prior art to render an invention obvious, it must render obvious the whole invention and not merely some part of the invention (*In re Antonie* 559 F.2d 618, 620, 195 USPQ 6,8 (CCPA 1997)). The prior art must also be considered as a whole including parts that teach away from Applicant's invention. Applicants respectfully submit that these criteria are not met in the Examiner's rejection.

Claims 6-8 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Charles et al (WO 92/17587), Montaraz et al (Infection and Immunity, 1985, 47: 744-751) or by Novotny et al (Infection and Immunity, 1985, 47: 744-751) in view of Akzo et al (EP 0 535 740 A1) and Garcon et al (WO 96/33739) and further in view of Acree et al (US Patent No. 4,567,042). Applicants' again based their response on the "Infection and Immunity, 1985, 50: 190-198" citation for Novotny.

The primary references are Charles, Montaraz, and Novotny. As the Examiner has acknowledged, these references do not teach vaccine compositions comprising a p68 antigen from *B. bronchiseptica* and an adjuvant, with the adjuvant comprising "saponin and a surfactant,

more particularly Quil A and cholesterol, nor do the primary references teach a method of protecting dogs against *B. bronchiseptica* comprising administering to a dog said vaccine."

All of the differences between the primary references and the instant application presented above in the discussion of the 102 rejections are applicable for this discussion regarding obviousness, including that none of the primary references teach a vaccine composition comprising p68 antigen for dogs against *Bordetella bronchiseptica*, wherein the antigen is produced recombinantly and lacking the signal sequence.

The Examiner states that "It would have been prime facie obvious to one of ordinary skill in the art that dogs could be one of the many animals to benefit from immunization with the p68 antigen." However, this is mere speculation on the part of the Examiner. None of the references cited by the Examiner indicate that p68 would be a protective antigen against *B. bronchiseptica* in dogs. None of the references cited by the Examiner discloses a vaccine composition comprising a recombinantly produced p68 antigen for dogs, nor a vaccine composition for dogs containing the claimed adjuvant, nor a method of protecting dogs against *B. bronchiseptica* comprising administering to a dog said vaccine. Identification of the problem does not negate the invention that solves the problem. The Supreme Court held that obviousness should be determined by looking at, among several factors, "objective evidence of nonobviousness." See Graham et al. v. John Deere Co. of Kansas City et al., 383 US 1 (1966). The Court further outlined factors that show such objective evidence as 1) recognition of the problem; 2) long-felt but unresolved needs; 3) failure of others; and 4) failed attempts to solve the problem.

As indicated in the Background section of the specification, prior to the present invention, there had been no showing that *Bordetella bronchiseptica* p68 antigen could be a safe and effective vaccine for dogs. In fact, contrary to the Examiner's allegation, as discussed above, Novotny expressly states that "vaccines from porcine strains performed poorly against challenge by canine strains and vice versa. Comparison of the mouse protection effect with the efficacy of the vaccine in SPF piglets showed no correlation in our studies." See page 197, right column, lines 9-11. Montaraz, et al., admit that even the possibility of using 68 kD protein as a vaccine for pigs still "requires extensive investigation." See page 750, right column, first paragraph. Therefore, the solution discovered by the Inventors of the present invention, that a vaccine

composition comprising recombinantly produced p68 antigen is safe and effective for dogs, is neither taught nor suggested by any of the cited art, and is not obvious in light of such art.

None of the cited references of Charles, Montaraz, Novotny, Akzo, Garcon, or Acree discloses the use of Quil A (an example of saponin) and cholesterol as an adjuvant for the p68 antigen. However, the Examiner alleges that Akzo lists saponins among possible adjuvants for *B. bronchiseptica* vaccines, and that Garcon teaches saponin and cholesterol as an adjuvant and *B. bronchiseptica* antigen as possible application for the adjuvant. Thus the Examiner alleges that by combining the cited art, it is obvious for a skilled artisan to replace the adjuvant used in any of the primary references with saponin, such as Quil A and cholesterol since the prior art (Akzo and Garcon) teach these adjuvants worked well in vaccines comprising *B. bronchiseptica* antigens.

Akzo is directed to a respiratory disease vaccine for cats (See Abstract), and merely discloses vaccines for cats employing killed or inactivated *Bordetella bronchiseptica* or fimbriaem from a native organism, which is a preferred *Bordetella bronchiseptica* subunit antigen. This reference does not teach a vaccine composition comprising p68 antigen for dogs against *Bordetella bronchiseptica*, wherein the p68 antigen is produced recombinantly, in combination with a saponin adjuvant. There can be no expectation of success that the vaccine compositions disclosed in Akzo for cats could be used in or modified for the vaccine compositions for dogs of the instant application.

Garcon is directed to saponin and cholesterol as an adjuvant and *Bordetella bronchiseptica* antigen as possible application for the adjuvant. However, Applicants have discussed the issues regarding the cited references above, and the mere teaching of saponin and cholesterol as a possible adjuvant for a *Bordetella bronchiseptica* antigen does not ameliorate the deficiencies in the cited references. For example, as discussed above, a p68 antigen for pig is suggested to be a poor vaccine for dogs. There is simply no teaching or suggestion in the references that coupling saponin and/or cholesterol can cure such defer. Moreover, Garcon does not suggest that saponin and/or cholesterol can be used in combination with the p68 antigen.

Acree is directed to vaccine compositions containing inactivated canine coronavirus, alone or in combination with other viral antigens. This reference does not teach a vaccine composition comprising p68 antigen for dogs against *Bordetella bronchiseptica*, wherein the p68

antigen is produced recombinantly. There can be no expectation of success that the vaccine compositions disclosed in Acree could be used in or modified for the vaccine compositions for dogs of the instant application.

In addition, Claims 6-8 and 11-13 all depend from claim 1 or from claims that ultimately depend from Claim 1. They thereby embody each and every element of Claim 1. Claim 10 comprises many of the elements of Claim 1. As discussed above, none of the cited art teaches a vaccine composition comprising p68 antigen for dogs employing a saponin and a surfactant, or Quil A and cholesterol, as an adjuvant. The mere teaching of saponin and cholesterol as a possible adjuvant for a *B bronchiseptica* antigen does not ameliorate the deficiencies of the cited references. For example, as discussed above, a p68 antigen for pigs is stated to be a poor vaccine component for dogs. There is simply no teaching or suggestion in the cited references that coupling saponin and/or cholesterol can cure such defect. Moreover, neither Akzo nor Garcon suggests that saponin and/or cholesterol can be used in combination with the p68 antigen.

Immunology is a highly unpredictable field, so that, while it may have been *obvious to try* identified antigens for use in vaccines and to try to combine antigens with known adjuvant because of the recognition of the problem and the unresolved need, there would have been no *expectation* of success. Akzo lists saponins among possible adjuvants for *B. bronchiseptica* vaccines (page 3, lines 42-44 and 56-57) and Garcon, which discloses the use of saponins and cholesterol as an adjuvant, lists antigens from *B. bronchiseptica* as possible applications for the saponin-cholesterol adjuvant (page 3, lines 19-20). As this merely points to the combination of an antigen from *B. bronchiseptica* with saponin and cholesterol as a candidate vaccine against *B. bronchiseptica,* without any specific expectation of success, nonobviousness must be acknowledged for the subject matter of claim 6-8 and 10-13. Thus the provision of a vaccine for dogs comprising an effective antigen or an effective combination of an antigen with a particular adjuvant is to be regarded as a valuable contribution to the art, for which nonobviousness should be acknowledged.

None of the references cited by the Examiner suggest Applicants' invention. In addition, Applicants respectfully submit that merely because the references can be combined, does not render the combination obvious. To support an obviousness rejection, the prior art must suggest the desirability of making the combination. *In re Fritch* (CAFC 1992) 972 F2d 1260, 23 PQ2d

1780. Before one determines that the prior art teaches one of ordinary skill in the art to make the changes necessary for the present invention, one must first determine that the prior art suggests that the references be combined. *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH* (CAFC 1989), 139 F3d 877, 45 PQ2d 1977. However, there is no indication in any of the references that would suggest they be combined. Also, there is no reasonable expectation that such a combination would be successful. Therefore, there would not have been any motivation to combine the teaching of Charles et al, Montaraz et al, or by Novotny et al, with Akzo et al, and Garcon et al, and further with Acree et al. Only hindsight would allow the Examiner to select bits and pieces of the prior art in an attempt to create a combination rejection, which is an inappropriate process.

The standard for obviousness is not combining what one can find in the prior art. It is inappropriate to use applicant's disclosure to assemble an argument. As discussed in *In re Papesch* (315 F.2d 318, 391, 137 USPQ 43, 51 CCPA 1963), "From the standpoint of patent law, a compound and all of its properties are inseparable; they are one and the same thing... There is no basis in the law for ignoring any property in making such a comparison" (based on the similarity of a compound's formula to the formula of another compound). Thus, it is inappropriate to ignore the properties that the Inventors of the current invention discovered.

Thus, although the Examiner states that "It would have been prime facie obvious to one of ordinary skill in the art that dogs could be one of the many animals to benefit from immunization with the p68 antigen." and "it would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the adjuvant used in any of the primary references with saponin, such as Quil A, and cholesterol since the prior art (Akzo and Garcon) teach these adjuvants worked well in vaccines comprising *B. bronchiseptica* antigens." this is not the standard for obviousness. The MPEP (2143.01) teaches that the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. However, there is no such suggestion in the references of the desirability of combining the references. There is nothing in the cited references to suggest that the disclosed vaccine or the disclosed method of protecting a dog could be used successfully in the present invention. As stated above, only hindsight has allowed the Examiner

to select bits and pieces of the prior art in an attempt to create a combination rejection, which is an inappropriate process.

The Applicants respectfully submit that none of the references cited by the Examiner suggest Applicants' invention. There is no indication in any of the references that would suggest that the references be combined with an expectation of success. Moreover, even when combined the references do not yield Applicants' invention. Accordingly, it is respectfully submitted that the methods, as presently claimed, are not rendered unpatentable over Charles et al, Montaraz et al, or by Novotny et al, in view of Akzo et al, and Garcon et al, and further in view of Acree et al. Thus, based on the remarks presented herein, the rejection of Claims 6-8 and 10-13 under 35 U.S.C. §103(a) is overcome. Because none of the references, alone or in combination, teaches Applicants' invention, withdrawal of the rejection is respectfully requested.

III. Conclusion

In view of the amendments and remarks made herein, Applicants respectfully submit that Claims 1, and 3-13 are in condition for allowance and request expedited notification of same.

Respectfully submitted,

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